

# Creating Artificial Barriers to Vaccinations

Richard G. Stefanacci, DO, MGH, MBA, AGSF, CMD

Achieving optimum outcomes is difficult enough without creating artificial barriers. Certainly none of us would ever admit to putting up any barrier that would prevent our residents from gaining access to important medical care; however, that is exactly what we have been doing by requiring signed consents for influenza and pneumococcal vaccinations in long-term care facilities. This is a serious issue—a nursing facility respiratory outbreak can easily infect almost two thirds of the residents resulting in complications in 20%.<sup>1</sup> With estimates as high as 70% for vaccinations reducing the risk of hospitalization and death in seniors it is difficult to imagine why any barriers, let alone artificially created ones, would exist.<sup>2,3</sup>

The authors of “Factors Predictive of Increased Influenza and Pneumococcal Vaccination Coverage in Long-Term Care Facilities: The CMS-CDC Standing Orders Program Project” demonstrated requiring signed consents is in fact a major barrier for achieving higher vaccination rates.<sup>4</sup> Similar results were documented in an earlier study published in the *Journal of the American Geriatrics Society*.<sup>5</sup> With a target of 90% set by the Healthy People 2010 and rates at 66% for influenza coverage and 39% for pneumococcal coverage we clearly cannot afford to be creating artificial barriers.<sup>6</sup>

In a 2004 article in the *Archives of Internal Medicine* the title of the publication zeroed in on this very issue: “Is signed consent for influenza or pneumococcal polysaccharide vaccination required?”<sup>7</sup> Their conclusion was that obtaining signed consent prior to administering vaccines represented an obstacle to achieving targeted goals for vaccinating individuals against influenza and pneumococcal disease. Further they found that signed consent is neither legally mandated (with the exception of the state of Maryland) nor a guarantee that the patient has been given signed consent.<sup>8</sup> Quite the opposite of safe guarding one legally by requiring informed there is an argument that any action taken by health care providers that reduces rates of vaccination such as requiring signed consents may create a legal liability similar to that of withholding recommended effective low-risk treatment such as aspirin therapy for the prevention of a myocardial infarction.

In addition, a previous *Archives of Internal Medicine* article highlighted the fact that one of the most fundamental and

pervasive myths about informed consent is that they must be obtained with a patient's signature on a consent form.<sup>9</sup> Clearly all therapies and treatments require informed consent, not signed consent. So where did the confusion about the requirement for signed consents for vaccination come from? It appears that part of the confusion comes from the misinterpretation of 2 federal acts. The Swine Flu Act of 1976 required that vaccine recipients be informed of the risks and benefits of vaccine. This act only applied to the 1976–1977 Swine Flu Immunization Program and was terminated in 1978.<sup>10</sup> The second act involves the National Childhood Vaccine Injury Act, which requires that the Centers for Disease Control and Prevention's vaccine information statement be provided prior to vaccination against diphtheria, tetanus, pertussis, measles, mumps, rubella, polio, hepatitis B, *Haemophilus influenzae* type b disease, varicella, and the pneumococcal conjugate vaccine used in children. This act does not have any requirements related to influenza and pneumococcal polysaccharide vaccinations, yet many have interpreted this incorrectly.<sup>11</sup>

Even the Centers for Medicare and Medicaid Services misstated this requirement in the question-and-answer section of their Web site, which has since been corrected.<sup>12</sup> In addition, tool kits designed by two national senior care provider associations to improve immunization rates are actually helping to create the artificial barrier of requiring signed consents. Currently the American Society of Consultant Pharmacists and American Medical Directors Association tool kits for vaccination include sample policy and procedure forms that require signed consent before a patient receives the influenza or pneumococcal vaccine.<sup>13,14</sup> This practice of requiring signed consents is inconsistent with the standard of care when prescribing other common treatments with relatively low risks and high benefits. In accepting this belief, the American Medical Directors Association is revising its tool kit for vaccination by removing the sample signed consent form.

Many LTC settings when asked why they require signed consent will most likely answer with one of two responses. Either because it is a regulatory requirement or rather that is how it has always been done. One will never hear that it is because of an effort to improve vaccination rates. Yet despite ample evidence regarding the effectiveness of vaccination in the prevention of influenza and pneumococcal outbreaks in LTC facilities, this is the response that facilities should be answering to justify their policy and procedures with regard to this matter.<sup>15–19</sup>

Of course while the requirement for signed consents may represent an artificial barrier there are other procedures that

---

Health Policy Institute, University of the Sciences in Philadelphia, Philadelphia, PA.

Address correspondence to Richard G. Stefanacci, DO, MGH, MBA, AGSF, CMD, Health Policy Institute, University of the Sciences in Philadelphia, 600 South 43<sup>rd</sup> Street, Philadelphia, PA 19104. E-mail: R.Stefan@usip.edu

Copyright ©2005 American Medical Directors Association

DOI: 10.1016/j.jamda.2005.07.001

can be put into place, yet often are not, that would improve vaccination rates. These include the development of clear and concise policy and procedures for facility-wide vaccinations as well as the use of standing orders. The Advisory Committee on Immunization Practices recommends standing orders programs in hospitals, nursing homes, and other health care facilities.<sup>20</sup> And for good reason. A recent study published in the *Journal of the American Medical Directors Association* also demonstrated the direct relationship between standing orders and higher vaccination rates in nursing homes.<sup>21</sup> Yet despite this there are several states such as California and New York that do not currently allow for standing orders. These state policies obviously inhibit the use of standing orders despite their documented benefit.<sup>22</sup>

In the end, health care providers should take a careful look at everything they do to make sure that they are not simply doing things out of habit but rather because it is based on clear evidence with an objective of improving care outcomes. Clearly we have not been doing that when we require signed consents for vaccination administration. Now is the time for us to improve outcomes by breaking down these artificial barriers and give our residents the shot they desire.

## REFERENCES

1. Monto AS, Terpenning MS. The value of influenza and pneumococcal vaccines in elderly. *Drugs Aging* 1996;8:445–451.
2. Nordin J, Mullooly J, Poblete S, et al. Influenza vaccine effectiveness in preventing hospitalizations and deaths in persons 65 years or older in Minnesota, New York, and Oregon. *J Infect Dis* 2001;184:665–670.
3. Monto AS, Hornbuckle K, Ohmit SE. Influenza vaccine effectiveness among elderly nursing home residents. *Am J Epidemiol* 2001;154:155–160.
4. Bardenheier B, Shefer A, McKibben L, Roberts H, Rhew D, Bratzler D. Factors predictive of increased influenza and pneumococcal vaccination coverage in long-term care facilities: The CMS-CDC Standing Orders Program Project. *J Am Med Dir Assoc* 2005;6:291–299.
5. Nichol K, Grimm MB, Peterson D. Immunization in long-term care facilities: Policies and practice. *JAGS* 1996;44:349–355.
6. Buikema A, Singleton J, Sneller V, Strikas R. Influenza and Pneumococcal Vaccination in Nursing Homes, US 1995–1999. Paper presented at the 35<sup>th</sup> National Immunization Conference, Denver, CO, 2001.
7. Kissam S, Gifford DR, Patry G, Bratzler D. Is signed consent for influenza or pneumococcal polysaccharide vaccination required? *Arch Intern Med* 2004;164:13–16.
8. Maryland Health-General Immunization against influenza virus and pneumococcal disease. Annotated Code of Maryland Health-Genera. 2002; statute 18-404.
9. Meisel A, Kuczewski M. Legal and ethical myths about informed consent. *Arch Intern Med* 1996;156(22):2521–2526.
10. Wecht CH. The swine flu immunization program: Scientific venture or political folly? *Am J Law Med* Winter 1977-78;3:425–445.
11. Centers for Disease Control and Prevention. All You Need to Know. Washington, DC; US Dept of Health and Human Services; May 4, 2000. Vaccine Information Statement.
12. Centers for Medicare and Medicaid Services. 2001 Q/A for Medicare Influenza/Pneumococcal Vaccination Benefits. Question 3. Available at: [www.cms.gov](http://www.cms.gov). Accessed April 11, 2002.
13. American Society of Consultant Pharmacists. 100% Immunization Campaign Resource Manual. Alexandria, VA: American Society of Consultant Pharmacist; 1999.
14. American Medical Directors Association. LTC Physicians Information Series: Immunization in Long Term Care. Columbia (MD). American Medical Directors Association; 1998.
15. Butler JC, Breiman RF, Campbell JF, et al. Polysaccharide pneumococcal vaccine efficacy. *JAMA* 1993;270:1826–1831.
16. Sisk JE, Moskowitz AJ, Whang W, et al. Cost-effectiveness of vaccination against pneumococcal bacteremia among elderly people. *JAMA* 1997;278:1333–1339.
17. Nichol KL, Wuorenma J, Von Sternberg T. Benefits of influenza vaccination for low, intermediate, and high risk senior citizens. *Arch Intern Med* 1998;158:1769–1776.
18. Mullooly JP, Bennett MD, Hornbrook MC, et al. Influenza vaccination programs for elderly persons: Cost effectiveness in a health maintenance organization. *Ann Intern Med* 1994;121:947–952.
19. Nichol KL, Baken L, Wuorenma J, Nelson A. The health and economic benefits associated with pneumococcal vaccination of elderly persons with chronic lung disease. *Arch Intern Med* 1999;159:2437–2442.
20. Centers for Disease Control and Prevention. Use of standing orders programs to increase adult vaccination rates: recommendations of the Advisory Committee on Immunization Practices. *MMWR Recomm Rep* 2000;49(RR-1):15–26.
21. deHart PM, Salinas SK, Barnette LJ, et al. Project Protect: Pneumococcal vaccination in Washington State nursing homes. *J Am Med Dir Assoc* 2005;6:91–96.
22. Shefer A, McKibben L, Bardenheier B, Bratzler D, Roberts H. Characteristics of long-term care facilities associated with standing order programs to deliver influenza and pneumococcal vaccinations to residents in 13 states. *J Am Med Dir Assoc* 2005;6:97–104.